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1632

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et. al.

**Serial No.:** 10/028,075

**Filed:** December 21, 2001

**For:** GENE REGULATOR

**Examiner:** T. McKelvey

**Group Art Unit:** 1632

**Attorney Docket No.:** 2183-5223US

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

January 7, 2004  
Date

*Betty Vowles*  
Signature

Betty Vowles  
Name (Type/Print)

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

Serial No.: 10/028,075

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US- 4,977,244	12-11-1990	Muchmore et al.
US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.
US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.
US- 5,958,413	09-28-1999	Anagnostopoulos et al.
US- 5,997,871	12-07-1999	Gallo et al.
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US- 6,583,109 B1	06-24-2003	Gallo et al.
US- 6,596,688 B1	07-22-2003	Gallo et al.
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US- 2002/0064501	05-30-2002	Khan et al.
US- 2002/0041871	04-11-2002	Brudnak
US-5,851,997	12-22-1998	Harris
US- 6,489,296	12-03-2002	Grinnell et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam
WO 98/35691	08-20-1998	Proscript, Inc.
WO 02/085117	10-31-2002	Eisai Co., Ltd.
DE 3715662	11-19-1987	The Wellcome Foundation Ltd.
DE 19953339	05-17-2001	Goldham Pharma GmbH
96/04008	02-15-1996	Government of the United States
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Biotechnology Institute

University of Maryland

Biotechnology Institute

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Biotechnology Institute

Other Documents

CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.

JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.

KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.

ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.

TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.

TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.

TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, J. Interferon Cytokine Res., 1999, pp. 911-21, Vol. 19.

MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.

MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.

**Serial No.: 10/028,075**

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 3077-5951US  
Serial No.: 10/409,027  
Filing Date: 4/8/2003  
Title: TREATMENT OF TRANSPLANT SURVIVAL

Attorney Docket No.: 3077-5952US  
Serial No.: 10/409,032  
Filing Date: 4/8/2003  
Title: TREATMENT OF TRAUMA

Attorney Docket No.: 3077-5953US  
Serial No.: 10/409,630  
Filing Date: 4/8/2003  
Title: TREATMENT OF MULTIPLE SCLEROSIS

Attorney Docket No.: 3077-5957US  
Serial No.: 10/409,642  
Filing Date: 4/8/2003  
Title: TREATMENT OF ISCHEMIC EVENTS

Attorney Docket No.: 3077-5958US  
Serial No.: 10/409,654  
Filing Date: 4/8/2003  
Title: TREATMENT OF NEUROLOGICAL DISORDERS

Attorney Docket No.: 3077-5960US  
Serial No.: 10/409,657  
Filing Date: 4/8/2003  
Title: STRATIFICATION

Attorney Docket No.: 3077-5956US  
Serial No.: 10/409,659  
Filing Date: 4/8/2003  
Title: PEPTIDE COMPOSITIONS



Serial No.: 10/028,075

Attorney Docket No.: 3077-5959US  
Serial No.: 10/409,668  
Filing Date: 4/8/2003  
Title: ADMINISTRATION OF GENE-REGULATORY PEPTIDES

Attorney Docket No.: 3077-5955US  
Serial No.: 10/409,671  
Filing Date: 4/8/2003  
Title: TREATMENT OF IATROGENIC DISEASE

Attorney Docket No.: 3077-5954US  
Serial No.: 10/409,694  
Filing Date: 4/8/2003  
Title: TREATMENT OF BURNS

Attorney Docket No.: 3077-4618.1US  
Serial No.: 10/678,995  
Filing Date: 10/3/2003  
Title: IMMUNOREGULATOR

This Supplemental Information Disclosure Statement is filed before the mailing date of the first Office Action on the merits; however, should a fee be required, please debit Deposit Account No. 20-1469.

Respectfully submitted,

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Date: January 7, 2004  
ACT/bv  
Enclosures: Form PTO/SB/08

Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/028,075
				Filing Date	December 21, 2001
				First Named Inventor	Khan et. al.
				Group Art Unit	1632
				Examiner Name	T. McKelvey
Sheet	1	of	2	Attorney Docket Number	2183-5223US

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		US- 5,958,413	09-28-1999	Anagnostopulos et al.	
		US- 5,997,871	12-07-1999	Gallo et al.	
		US- 6,319,504 B1	11-20-2001	Gallo et al.	
		US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		US- 6,583,109 B1	06-24-2003	Gallo et al.	
		US- 6,596,688 B1	07-22-2003	Gallo et al.	
		US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2002/0064501	05-30-2002	Khan et al.	
		US- 2002/0041871	04-11-2002	Brudnak	
		US-5,851,997	12-22-1998	Harris	
		US- 6,489,296	12-03-2002	Grinnell et al.	

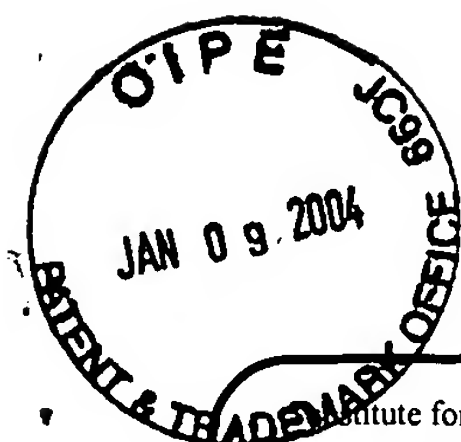
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		WO 98/35691	08-20-1998	Proscript, Inc.		
		WO 02/085117	10-31-2002	Eisai Co., Ltd.		
		DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
		DE 19953339	05-17-2001	Goldham Pharma GmbH		
		96/04008	02-15-1996	Government of the United States		
		97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		97/49432	12-31-1997	University of Maryland Biotechnology Institute		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Institute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(use as many sheets as necessary)*

Sheet

2

of

2

**Complete if Known**

Application Number

10/028,075

Filing Date

December 21, 2001

First Named Inventor

Khan et. al.

Group Art Unit

1632

Examiner Name

T. McKelvey

Attorney Docket Number

2183-5223US

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.	
		JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.	
		KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.	
		ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.	
		TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
		TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, J. Interferon Cytokine Res., 1999, pp. 911-21, Vol. 19.	
		MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	

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<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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